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(MA)  
[cb]

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/025,378	12/18/2001	Christopher C. Lawrence	9793/74	5414

7590 03/04/2004  
MARYLN L. AMICK  
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EXAMINER

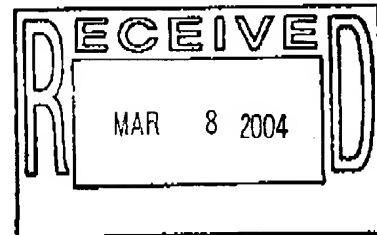
CEPERLEY, MARY

ART UNIT PAPER NUMBER

1641

DATE MAILED: 03/04/2004

Please find below and/or attached an Office communication concerning this application or proceeding.



RECEIVED: IPLD  
INITIALS: 3/8/04  
DOCKETED: 6/4/04  
(9/9/04)

<b>Office Action Summary</b>	<b>Application No.</b> 10/025,378	<b>Applicant(s)</b> LAWRENCE ET AL.	
	<b>Examiner</b> Mary (Molly) E. Ceperley	<b>Art Unit</b> 1641	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-28 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-28 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |   |  |
|---|--|
| <p>1) <input type="checkbox"/> Notice of References Cited (PTO-892)</p> <p>2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)</p> <p>3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br/>Paper No(s)/Mail Date <u>5</u>.</p> | <p>4) <input type="checkbox"/> Interview Summary (PTO-413)<br/>Paper No(s)/Mail Date. ____</p> <p>5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)</p> <p>6) <input type="checkbox"/> Other: ____</p> |
|---|--|

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1) The following problems must be addressed.

a) Reference A22 of form PTO-1449 is missing a publication date. Without a publication date, the printer will not cite this reference on the front of any patent which might issue based on this application.

b) Serial numbers of pending applications are missing from pages 8 and 13 of the specification.

2) Although specific claims are cited in the rejections below, these rejections are also applicable to all other claims in which the noted problems/language occur.

3) The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

4) The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

5) Claims 1-28 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for the preparation of a "reagent" comprised of CDI-activated "particles" to which an antibody is attached through the CDI moiety, does not reasonably provide enablement for a reagent in which the antibodies are attached to the "particles" through any other point of attachment. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims. The claims, as written, include the case wherein the antibody can be bound to the particle surface at any location and

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through any linkage ("linked to the surface through a covalent bond"). According to the language of claim 1, the use of the CDI-activated functionality on the particle is not required for the formation of the "covalent bond" between the particle and antibody. There is no enabling support for attachment of the antibody at any location other than through the CDI functionality.

**6)** Claims 1-28 are rejected under 35 U.S.C. 112, second paragraph, as being Indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

**a)** The claims are indefinite in not specifying where the antibodies are attached to the "particles" (see paragraph 5) above).

**b)** Claim 6 is a product claim ("reagent") which contains an improper method of use limitation ("forms an assay mixture when mixed with a sample"). The limitation on the concentration of tertiary amine in the "assay mixture" is improper since the claim is drawn to the "reagent" which contains no sample (see also, claim 13).

**c)** It is unclear what is meant by the claim 1 term "a binding agent" since the claim fails to indicate the nature/reactivity/specificity of the moiety which is to be bound to the particles.

**d)** In claim 17, there is no requirement that the "antibody" be the "binding agent" recited in claim 1 nor is there any requirement for where and how the "antibody" is placed on the "reagent". For these reasons the claim is indefinite and confusing. See also, claims 18-20.

**e)** Claim 25 is indefinite and confusing in not specifying that the "binding agent" is specific for the "analyte".

**7)** WO 02/03068 A1 is cited to show the state of the art. See the abstract.

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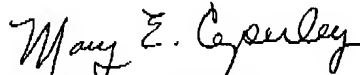
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An inquiry of a general nature which is not related to the prosecution on the merits should be directed to Technology Center 1600 telephone number (571) 272-1600. The general fax number for the USPTO is (703) 872-9306.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mary (Molly) E. Ceperley whose telephone number is (571) 272-0813. The examiner can normally be reached from 8 a.m. to 4:30 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long V. Le, can be reached on (571) 272-0823.

March 02, 2004

  
Mary (Molly) E. Ceperley  
Primary Examiner  
Art Unit 1641